

REMARKS

The Office Action has withdrawn Claims 74-75 from consideration, for allegedly being directed to an invention that is independent and distinct from the invention originally elected. In addition, it has rejected claims 71-73 and 86-87 under 35 U.S.C. §102(a) as defining subject matter which is allegedly anticipated by the teachings to an article Chang et al. in JACS 124, 1856-1857 (2002) (“Chang et al.”). Further, Claims 71-72 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in JP-051/163203 (“JP ‘203”). Further, Claims 71-73, 76-77 and 85-86 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in U.S. Patent No. 4,877,789 to Shroot, et al. (“Shroot et al.”). In addition, claims 71-72 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings of JP-01/201352 (“JP ‘352”). Further, Claims 1, 2 and are rejected under 35 U.S.C. §102 (b) as defining subject matter which is allegedly anticipated by the teachings of U.S. Patent No. 4,797,408 to McGovern et al. (“McGovern et al.”). Claims 1, 2 and 68 are further rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in U.S. Patent No. 5,455,273 to Maier et al. (“Maier et al.”). In addition, Claims 1-2 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in U.S. Patent No. 3,941,783 to Grega et al. (“Grega et al.”). Moreover, Claims 1-2, 35, 68, 71-73 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in U.S. Patent No. 3,995,059 to Fukumaru et al. (“Fukumaru et al.”). Furthermore, Claims 71-73 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in JP/01-201325 (“JP ‘325”). Finally, Claims 10, and 85-86 are rejected under 35 U.S.C. §112, second paragraph as allegedly failing to

particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Moreover, Claims 3-9, 36, and 78-84 are objected as being dependent upon a rejected claim, but the Office Action has indicated that they would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

The Office Action has maintained and made final its restriction requirement to Claims 11-34, 37-61, 64-67 and 69-70. Applicants respectfully request reconsideration thereof in view of the comments made in the Response dated September 5, 2006 and incorporate the same by reference as if fully set forth herein.

The Office Action has additionally withdrawn Claims 74-75 from consideration as defining subject matter which is patentably distinct from the elected subject matter, i.e., the subject matter in Claims 1-10, 35, 36, 68, 71-73, and 76-87. Although the subject matter in Claims 74-75, is withdrawn applicants have not abandoned the subject matter therein and reserve the right to file a divisional application directed to the subject matter therein.

Nevertheless, applicants respectfully submit that the subject matter in claims 74 and 75 is not patentably distinct from the subject matter recited in the elected invention .

The subject matter recited in Claims 74 and 75 is directed to amide hydrates of tertiary amides, i.e., the subject matter of Claims 76 et. seq., which has already been searched by the United States Patent and Trademark Office (“USPTO”). Claims 74 and 75 are not process claims; but rather are product claims, and are more precisely product by process claims of hydrates of tertiary amides. Moreover, the Office Action has already conducted a search on the tertiary amides of the present invention. Thus, contrary to the allegations in the Office Action,

the subject matter therein is encompassed by the search already performed by the U.S. Patent and Trademark Office and currently being examined by the USPTO.

In addition, it is respectfully submitted that the Restriction Requirement with respect to Claims 74 and 75, be withdrawn since it is not in compliance with 35 U.S.C. §121 and 37 C.F.R. §§1.141 and 1.142.

35 U.S.C. §121 provides that the Commissioner may restrict an application when two or more independent and distinct inventions are claimed in a single application (emphasis added). Similarly, 37 C.F.R. §1.141(a) permits restriction on condition that independent and distinct inventions are found within one application. There is absolutely no indication in the Office Action that the subject matter in claims 74-75 are independent from the elected subject matter.

MPEP §808 defines independent as follows:

The term independent (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects discussed, that is, they are unconnected in design, operation or effect.

The subject matter of Claims 74 and 75 is directed to hydrates of tertiary amides, that is, a tertiary amide bonded to a water molecule. The subject matter of Claims 1-10, 35 and 36, 68, 71-73 and 87 are directed to tertiary amides while the subject matter in claims 74-85 are directed to tertiary amide hydrates. Thus, the subject matter in all of the claims has the tertiary amide core structure in common. Thus, the subject matter in claims 74 and 75 are not independent from the subject matter of Claims 1-10, 35, 68 and 71-73 and 76-87.

Moreover, the subject matter in Claims 74 and 75 is not distinct from the subject matter in claims 1-10, 35, 68, 71-73 and 76-87. Although the subject matter in claims 74 and 75 are described in process parameters, the subject matter therein is directed to hydrates of tertiary amides, that is, it is direct to products. Thus, the search for the subject matter in claims 74 and

75 overlaps with the search for Claims 1-10, 35, 68, 71-73 directed to tertiary amides, and especially Claims 76-86 directed to tertiary amide hydrates.

Thus, the subject matter in Claims 74 and 75 is encompassed by the search already performed. Consequently, the subject matter in claims 74- and 75 is not independent and is not distinct from the elected subject matter. It is respectfully submitted that the restriction requirement with respect to Claims 74 and 75 is in error; withdrawal thereof is respectfully requested.

It is vital to all applicants that the restriction requirement issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application “shall not be used as a reference” against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that 35 U.S.C. § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), that court held that §121 does not insulate a patentee from an allegation of “obviousness-type” double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

In addition, the Courts have recognized the advantages to the public interest to permit patentees to claim all aspects of their invention, as the applicants have done herein, so as to encourage the patentees to make a more detailed disclosure of all aspects of their invention. The CCPA has observed:

We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects of what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456, F.2d 658, 666, 177 U.S.P.Q. 250, (CCPA 1973).

Furthermore, applicants respectfully request that in view of increased Official Fees and the potential limitation of applicants' financial resources, a practice which arbitrarily imposes a Restriction Requirement may become prohibitive, and thereby contravenes the constitutional intent to promote and encourage the progress of science and the useful arts.

Therefore, applicants respectfully request that the subject matter of claims 74-75 be examined in this application and not be withdrawn.

Before addressing the merits of the rejections, it should be noted that applicants have amended Claims 5 and 35 by amending the definition of R₅ to exclude lower alkyl. In addition, applicants have cancelled Claim 73 and have rewritten the subject matter therein in Claim 88 in

independent form. Further, Claim 88 has been amended as Claim 1 and 35 by reciting that the term fatty groups is defined as being completely saturated or containing 1-8 carbons – carbon double bonds, consistent with the definition in Paragraph 29 of the instant application.

Applicants have added Claim 89 which is supported by the disclosure in Paragraph 40 of the instant specification. Applicants have cancelled claims 71 and 72 without prejudice; they have not abandoned the subject matter therein and reserve the right to file a divisional application thereto.

No new matter has been added to the application.

It is to be noted that Claims 71 and 72 have been cancelled. Thus, the various rejections in the Office Action in relation thereto have been rendered moot.

Pursuant to the rejection of Claims 88 (old Claim 73) and 86-87 under 35 U.S.C. §102(a), the Office Action cites Chang et al.

Chang et al. disclose various amides; however, it only discloses a single type of tertiary amide on page 1856. Except for the tertiary amide formed from a diamine designated therein as DT, all of the other ceramides described therein are secondary amides, not tertiary amides. The one type of tertiary amide described therein has the two substituents attached to the nitrogen atom of the amido group as being an unsubstituted alkyl group having 14 carbon atoms. As recited in Claim 88 of the present application, the two substituents attached to the nitrogen atom of the amido group are not a C₁₄ alkyl group. More specifically, in the tertiary amides recited in the rejected claims, the two groups attached to the nitrogen atom of the amide, designated herein as R₅ and R₆, are independently aryl, aryl lower alkyl or a fatty group containing 11-29 carbon atoms and 1-8 carbon-carbon double bonds or R₇, which is a diether. In other words the fatty

group contains at least one carbon-carbon double bond. Thus, neither R₅ nor R₆ is an unsubstituted alkyl group, let alone an unsubstituted alkyl group containing 14 carbon atoms.

The subject matter in Claim 86 is directed to a composition containing a tertiary amide hydrate of the subject matter of Claims 76-85, i.e., the compounds recited therein are directed to tertiary amides wherein a molecule of water is associated therewith. None of the compounds described in Chang et al. are tertiary amide hydrates. Further, the subject matter in Claim 86 has the same definition of R₅ and R₆ as in Claim 88. Thus, for the reasons given hereinabove, the subject matter in Claim 86 is not described in Chang et al. Finally, Claim 87 is directed to distearyl linoleamide, or pharmaceutically acceptable salt thereof, i.e., the groups therein attached to the nitrogen atom contains 18 carbon atoms, and not the 14 carbon atoms disclosed in Chang et al. Thus, the subject matter recited in Claims 86, 87 and 88 of the present application do not have two fatty groups on the nitrogen atom wherein both of the groups contain 14 carbon atoms. Thus, the subject matter of Claims 86-88 are not described or taught in Chang et al.

Case law has held that anticipation requires that the prior art reference describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation. Atlas Power Co. v. Ireco, Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999) The exclusion of a claimed element from a prior art reference is enough to negate anticipation by the reference. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-772, 218 USPQ781, 789 (Fed. Cir. 1983).

As described above, the claimed invention recited in Claims 86-88 does not encompass a tertiary amide described in Chang et al. Thus, the rejection of Claims 86-88 under 35 U.S.C. §102(b) is obviated. Withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 71-72 under 35 U.S.C. §102(b), the Office Action refers to JP '203 and JP '352. Inasmuch as applicants have cancelled Claims 71 and 72 without prejudice, these rejections are rendered moot.

Pursuant to the rejection of Claims 88 (old Claim 73), 76-77 and 85-86, the Office Action cites Shroot et al.

Shroot, et al. disclose tertiary amides wherein the substituent on the acyl carbon of the amide has a carbon-carbon triple bond. The subject matter defined in the rejected claim does not encompass any amides where there is a carbon-carbon triple bond in one of the substituents on the acyl carbon atom or the nitrogen atom of the amide. The substituted group on the acyl carbon in the present application is either saturated or contains 1-8 carbon-carbon double bonds. In other words, there are no carbon-carbon triple bonds present as a substituent on the acyl carbon of the compounds described in Claims 76-77 and 85-86, or 88. Thus, Shroot et al. do not anticipate the subject matter of the rejected claims.

Moreover, with respect to the subject matter in Claims 76 et seq. besides the above distinction, the subject matter therein is directed to tertiary amide hydrates. On the other hand, there is no teaching or disclosure in Shroot et al. of any tertiary amide hydrates.

Thus, there are differences between the claimed subject matter in the rejected claims and the teachings in Shroot et al. Consequently, the rejection of Claims 76-77, 85-86 and 88 under 35 U.S.C. §102(b) is obviated. Withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 1, 2 and 68 under 35 U.S.C. §102(b), the Office Action cites McGovern et al.

McGovern et al. disclose tertiary amides where the nitrogen atoms of the amido group are part of a ring structure. On the other hand, as contemplated by the compounds of the present

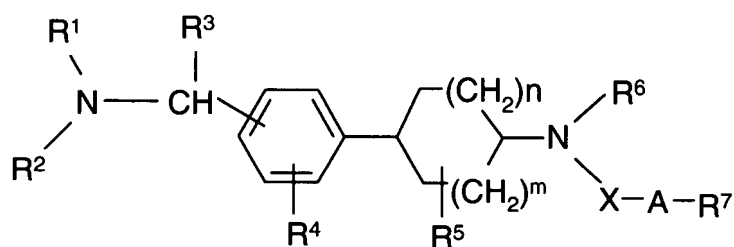
invention, the substituents on the amido nitrogen are R_5 and R_6 wherein R_5 is aryl, aryl lower alkyl or fatty group containing 11-29 carbon atoms or R_7 , and R_6 is aryl, aryl lower alkyl or R_7 ,

wherein R_7 is $R_1 - Ar - O - R_2 - O - R_3 -$

Thus, as defined in the rejected claims, R_5 and R_6 are not defined to include a structure in which R_5 and R_6 when taken together with the nitrogen atom to which they are attached form a ring. Thus, McGovern et al. do not anticipate the present invention. Thus, the rejection of Claims 1, 2 and 68 under 35 U.S.C. §102(b) is obviated. Withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 1, 2 and 68 under 35 U.S.C. §102, the Office Action cites Maier et al. ("Maier et al.")

Maier et al. disclose N,N-disubstituted aryl cycloalkylamines of the formula



wherein n represents the number 1 or 2, m represents the number 0 or 1,

A denotes a single bond, a straight-chained or branched C_{1-17} -alkylene group, a C_{2-17} -alkenylene group or a C_{2-6} -alkynylene group,

X is a carbonyl or sulphonyl group,

R^1 is a straight-chained or branched C_{1-5} -alkyl group,

R^2 is a straight-chained or branched C_{1-5} alkyl group which may be substituted by one or two hydroxy groups, by an alkoxy or by an alkylcarbonyloxy group having 1 to 5 carbon atoms in the alkyl moiety, the alkyl moiety being straight-chained or branched, by an alkoxycarbonyloxy group, whilst the above-mentioned substituents may not be bound in position 1 of the alkyl group and two of these groups may not be bound to the same carbon atom, or by an aminocarbonyl, alkylaminocarbonyl, diakylaminocarbonyl, cyano or alkylcarbonyl group,

R^3 , R^4 and R^5 which may be identical or different, each denote a hydrogen atom or an alkyl group,

R^6 denotes a hydrogen atom, a straight-chained or branched C_{1-6} -alkyl group, a C_{3-6} -cycloalkyl group, an allyl or propargyl group or an optionally halogen-substituted benzyl group,

R^7 denotes a hydrogen atom, a C_{3-6} -cycloalkyl group, a phenyl group optionally substituted by an alkyl group, by one or two halogen atoms or by a trifluoromethyl group, or R^7 denotes a naphthyl or tetrahydronaphthyl group or a thienyl group optionally substituted by a halogen atom or by an alkyl group,

whilst A cannot be a single bond if X is a sulphonyl group and R^7 is a hydrogen atom, and

unless otherwise specified the above-mentioned alkyl and alkoxy moieties may each contain 1 to 3 carbon atoms and the above-mentioned halogen atoms may each denote a fluorine, chlorine or bromine atom.

As defined, one of the substituents on the amido nitrogen atom in Maier et al. is aminoalkylphenyl cycloalkyl. The compound contemplated by the present invention does not contemplate any cycloalkyl group attached to the amido nitrogen atom. Thus, the subject matter

of Claims 1, 2 and 68 are thus not anticipated by the teachings of Maier et al and the rejection under 35 U.S.C. §102(b) is obviated. Withdrawal thereof is respectfully requested.

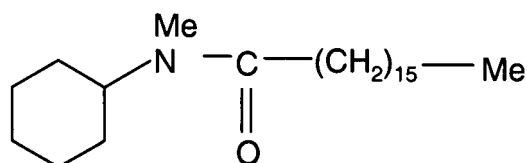
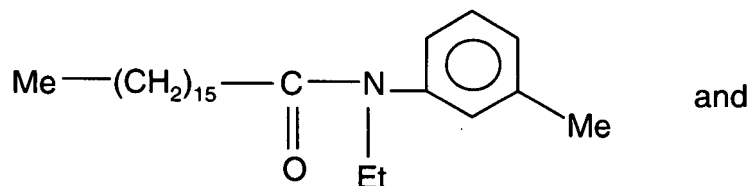
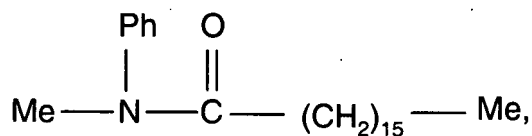
Pursuant to the rejection of Claims 1 and 2 under 35 U.S.C. §102(b), the Office Action cites Grega et al. ("Grega et al.").

According to the Office Action, Grega et al. disclose the compound N-phenyl,N-isopropyl-hexadecamide. This compound requires that one of the groups on the nitrogen amido atom is an isopropyl group. However, the rejected claimed subject matter of the present invention does not contemplate any unsubstituted lower alkyl group on the nitrogen atom; that is, as defined in Claim 1, R₅ is aryl lower alkyl, a fatty group containing 11-29 carbon atoms or R₇, while R₆ is aryl, aryl lower alkyl or R₇ wherein R₇ is a diether substituent as defined.

Thus, Grega et al. do not teach or disclose the claimed subject matter of Claims 1 and 2. Thus, the rejection of Claims 1 and 2 is not anticipated by the subject matter described in Grega et al. Therefore, the rejection of Claims 1 and 2 under 35 U.S.C. §102(b) is obviated. Withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 1-2, 35, 68, 71, 72, and 88 (old Claim 73) under 35 U.S.C. §102(b) the Office Action cites Fukumaru et al. ("Fukumaru et al.").

The Office Action refers to the Abstract, alleging that it teaches the following compounds:



The Office Action alleges that these compounds anticipate the subject matter recited in Claims 1, 2, 35, 68 and 88 (old Claim 73). In all of these examples, at least one of the substituents on the amido nitrogen is an unsubstituted lower alkyl group.

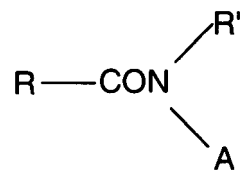
The subject matter in the rejected claims does not have any unsubstituted lower alkyl substituent on the amido nitrogen atom. As defined in the rejected claims of the present application, R_5 is aryl, aryl lower alkyl or fatty group containing 11-29 carbon atom or R_7 and R_6 is aryl, aryl lower alkyl or R_7 wherein R_7 is the diether substituent described herein. Thus, the rejected claimed subject matter does not have an unsubstituted lower alkyl group on the amido nitrogen atom. Thus, there are differences between the claimed subject matter in the rejected claims and Fukumaru et al. Consequently, the rejection of Claims 1, 2, 35, 68 and 88 under 35 U.S.C. §102(b) is obviated; withdrawal is respectfully requested.

Pursuant to the rejection of Claim 88 (old Claim 73) under 35 U.S.C. §102(b), the Office Action cites JP 01/201325.

Applicants respectfully submit that the number JP 01/201325 is a mistake. There is no listing on the PTO 892 Form of a reference having that number. Applicants respectfully submit that two of the numbers have been transposed and that the reference was meant to be JP 01/201352, which was made of record. Clarification is respectfully requested.

Assuming that the reference was intended to be JP '352, JP '352 does not anticipate the present invention. Before addressing the merits of the rejections, applicants are submitting herewith a translation of JP '352. Applicants are listing this on a PTO 1449 form; it is respectfully requested that this translation be made of record herein.

JP '352 discloses a styrene resin compound comprised of 0.01-5 parts content by weight per 100 parts per weight of compound of general formula (1) in a styrene group resin of the formula



where R is an alkyl group or alkenyl group of 7-21 carbon atoms, R' is an alkyl group or alkenyl group of 8-22 carbon atoms, A is an alkyl group or alkenyl group of 8-22 carbon atoms or a hydrogen atom and one or both of R and R' is an alkenyl group.

It is respectfully submitted that the compounds therein are as described as being useful as a lubricant. There is no teaching or suggestion therein of the use of the compounds in a pharmaceutical composition.

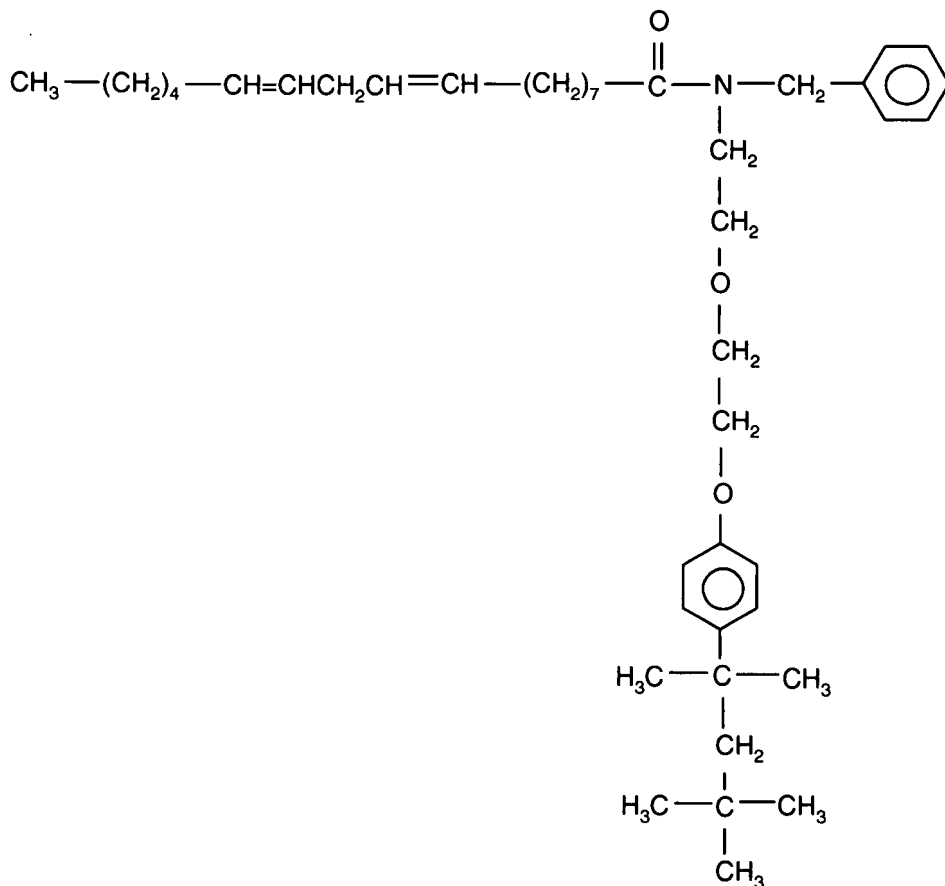
Claim 88 is directed to a pharmaceutical composition. However, since JP '352 is not directed to a pharmaceutical composition, there is at least one difference between the subject

claimed and the teaching therein. Thus, the rejection of Claim 88 under 35 U.S.C. §102(b) is obviated. Withdrawal thereof is respectfully requested.

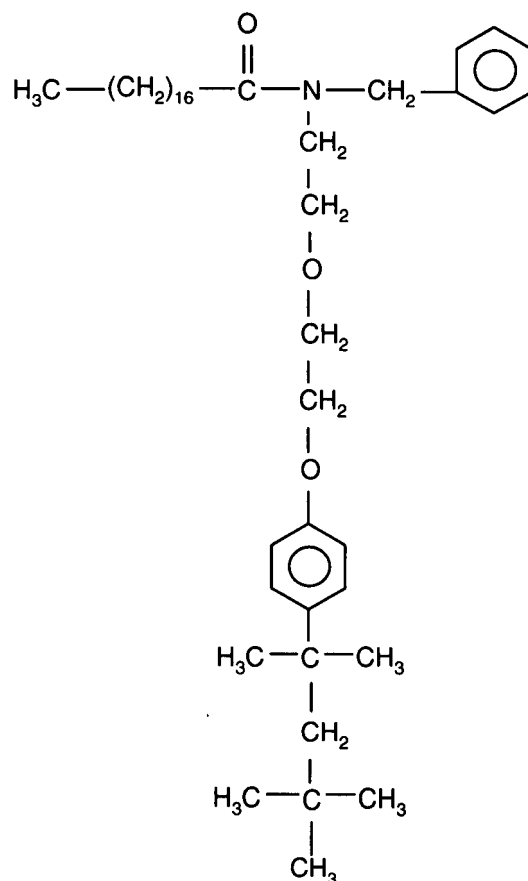
Pursuant to the rejection of claims 10, 85 and 86, under 35 U.S.C. §112, second paragraph, the Office Action alleges that there is insufficient antecedent basis for the subject matter therein.

Contrary to the allegations in the Office Action, these compounds are within the scope of the claims. Reference is made to paragraph 42 on page 9 of the instant specification, which indicates that these two compounds, contrary to the Office Action's allegations, are examples of tertiary amides.

The structure of benzethonium linoleamide is:



while that of benzethonium stearamide is

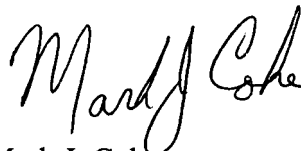


Thus, there is antecedent basis for the subject matter recited in Claims 10, 85 and 86. More specifically, R₅ is benzyl, R₆ is R₇ and R₄ is a fatty group. Therefore, the rejection of Claims 10, 85 and 86 under 35 U.S.C. §112, second paragraph is obviated. Withdrawal thereof is respectfully requested.

The Office Action has objected to Claims 3-9, 36 and 78-84, for being dependent upon a rejected base claim. However, in view of the above, the objections to Claims 3-9, 36 and 78-84 are overcome; withdrawal thereof is respectfully requested.

Thus, in view of the Amendment to the Claims and the Remarks hereinabove, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mark J. Cohen". The signature is fluid and cursive, with the first name "Mark" and last name "Cohen" clearly distinguishable.

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